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Bruce J. Gantz

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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/518,811
Filing Date: July 11, 2005
Appellant(s): GANTZ ET AL.

Michael G. Verga
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/14/2009 appealing from the Office action mailed 10/4/2007. The Examiner's answer submitted 9/9/2009 has been reviewed.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on January 04, 2008 has not been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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5143090	DUTCHER	09-1992
6163729	KUZMA	12-2000
4487210	KNUDSEN	12-1984

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 8-10, 13, 22, 25, 36-39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (WO 00/69513) in view of Dutcher (US 5153090).

Regarding claims 1 and 9, Kuzma discloses the same invention as claimed, including an elongate carrier 12 (Figure 1A, 1B), a plurality of electrodes 14 in the carrier, and a stabilizing collar 18 adjacent to the carrier having an abutment surface 19 configured to abut a surface of the cochlea (Figure 2). Kuzma further discloses anchors 16 configured to prevent translation of the carrier along the longitudinal axis of the carrier. Kuzma does not disclose an anchor configured to prevent rotation. However, Dutcher teaches using a porous polyester fiber mesh (Col. 5, lines 29-31; Figure 5), in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claim 2, Kuzma discloses the collar having a first collar portion having a greater diameter than the carrier (Figure 1A).

Regarding claim 3, Kuzma discloses the distal end of the collar means 19 comprising the abutment surface (Figure 1A).

Regarding claim 4, Kuzma discloses the abutment surface extending at substantially a right angle to the carrier (Figure 1A).

Regarding claim 6, Kuzma discloses the collar means formed integrally with the carrier member (Figure 1A).

Regarding claim 8, Kuzma discloses the anchoring means extending adjacent the abutment surface (Figure 1A).

Regarding claims 10, Kuzma does not disclose mesh material molded within the collar. However, Dutcher further teaches including the mesh material with the collar of the lead, in order to insure a secure connection of the electrodes (Col. 5, lines 29-32; Figures 5 and 6). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the molding the mesh material with the collar of Dutcher with the device of Kuzma for the purpose of insuring a secure connection of the electrodes.

Regarding claim 13, Kuzma discloses the electrode array being insertable to a depth at the first basal turn of the cochlea (Figure 2).

Regarding claim 22, Kuzma discloses the same invention as claimed, including forming an opening into the cochlea (Page 8, lines 11-13; Figure 2), inserting the electrode array (Page 8, lines 13-21), and abutting a collar (Page 8, lines 16-21, 23-24). Kuzma further discloses securing the electrode array to prevent translation along a longitudinal axis of the array (Page 8, lines 21-24). Kuzma does not disclose securing the electrode array to prevent rotation. However, Dutcher teaches using a porous polyester fiber mesh (Col. 5, lines 29-31; Figure 5), in order to enhance tissue ingrowth

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to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claim 25, Kuzma further discloses attaching the anchor to the recipient adjacent the formed opening (Page 8, lines 21-24).

Regarding claim 37, Kuzma further discloses halting insertion when the array is at the first basilar turn of the cochlea (Figure 2).

Regarding claims 38 and 39, Kuzma discloses the same invention as claimed, including means for abutting 19 (Figure 2), and means for anchoring 16 to prevent translation along the longitudinal axis of the array. Kuzma does not disclose a means for anchoring configured to prevent rotation. However, Dutcher teaches using a porous polyester fiber mesh (Col. 5, lines 29- 31; Figure 5), in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claims 41-43, Kuzma further discloses the abutment surface sealing the opening in the cochlea (Figure 2; Page 8, lines 16-21).

Claims 12, 36, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claim 1 above, and further in view of Kuzma (US 6163729).

Regarding claims 12, 36, 40, Kuzma '513 does not disclose an indicator means on the collar. However, Kuzma '729 teaches the use of an indicator 203 provided on the collar (Figure 2), for the purpose of preventing the electrode from being inserted too deep (Col. 6, line 65-Col. 7, line 17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the indicator of Kuzma '729 with the device of Kuzma '513, in order to prevent the electrode from being inserted too deep. The Office notes that the indicator of Kuzma '729, being on the same side as the electrodes, as shown in Figures 2 and 10, is configured to indicate the rotational orientation of the electrode array. Kuzma '513 further discloses orienting the array during insertion (Page 7, lines 26-29).

Claim 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claim 22 above, and further in view of Knudsen et al. (US 4487210).

Regarding claims 23 and 24, Kuzma does not disclose fabricating a fascia washer and placing it over the electrode. However, Knudsen discloses fabricating a fascia washer from tissues from the head (Col. 2, lines 3-5), which is considered equivalent to Appellant's temporalis fascia harvested from recipient, and packing it around the lead, which is considered equivalent to placing it over the electrode array, for the purpose of anchoring the leads in place. Knudsen does not disclose placing the fascia washer over the electrode prior to insertion into the cochlea. However, it would have been obvious to place the fascia washer on the electrode prior to insertion since such a modification would have involved a mere change in sequence. A change in sequence is generally recognized as being within the level of ordinary skill in the art. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959), *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the fabricating a fascia washer from temporalis fascia and placing it over the electrode array of Knudsen with the method of Kuzma, for the purpose of anchoring the electrode array in place.

(10) Response to Argument

A. No motivation

Appellant asserts the technical features of Kuzma already provide the benefits of securing the electrode array at the implantation site, and thus, there is no motivation to further combine with the mesh of Dutcher. However, as noted in the Final Rejection and

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Advisory Action, adding the mesh of Dutcher to the invention of Kuzma would more firmly fix the electrode array to the target tissue than the features of Kuzma alone. The mesh of Dutcher does not duplicate the securing efforts, as Appellant appears to suggest. The mesh of Dutcher enhances the ability to secure the electrode array firmly to target tissue. Thus, there is motivation to combine Kuzma with Dutcher because the combination offers an improvement in security of attachment to target tissue.

B. Unsatisfactory for intended purpose

Appellant asserts combining Dutcher with Kuzma renders Kuzma unsatisfactory for its intended purpose, because the mesh of Dutcher performs the functions of the features of Kuzma. However, firstly, the device of Kuzma is not rendered unsatisfactory, because the features of Kuzma cooperate in tandem with the added mesh of Dutcher. There is no loss of functionality. Secondly, tissue ingrowth takes time, a fact which is commonly known in the art. The features of Kuzma perform stabilizing and anchoring functions up to and including the time when tissue ingrowth on the mesh begins to provide a firm fixation.

C. Substantial modifications

Appellant asserts substantial modifications must be made to the device of Kuzma to incorporate the mesh of Dutcher when the device is inserted at an angle as shown in Figure 5 of Kuzma. However, as noted in the Final Rejection and Advisory Action,

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Figure 5 of Kuzma shows an alternate embodiment, whereas Figure 2 shows the primary embodiment of Kuzma. Adding the mesh of Dutcher to the embodiment in Figure 2 of Kuzma would require only simple modifications within the grasp of one with ordinary skill in the art. Furthermore, with either embodiment shown in Figures 2 or 5 of Kuzma, it is a simple modification to add the mesh of Dutcher, since the mesh is flexible and conforms to surrounding tissue, regardless of insertion angle.

For these reasons above, the rejection by Kuzma and Dutcher stands.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted

Michael Chu

/MICHAEL CHU/

Examiner, Art Unit 3766

Conferees:

/Carl H. Layno/

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